codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

JOINT OFFICE: Viale delle Terme di Caracalla 00100 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

Agenda Item 3 **CX/MAS 04/3**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING
Twenty-fifth Session
Budapest, Hungary, 8 – 12 March 2004

DRAFT GENERAL GUIDELINES ON SAMPLING
GOVERNMENT COMMENTS AT STEP 6
(European Community, Finland, Hungary, Japan, New Zealand, United States)

EUROPEAN COMMUNITY

Draft General Guidelines on Sampling (ALINORM 03/23, para. 19, Appendix IV) - Section 2.4

- First case
  Repeatability standard deviation is negligible compared to sampling standard deviation if the measurement standard deviation is at most $\frac{1}{3}$ of the sampling standard deviation. In this case only 5 % of the standard deviation of the observed results will be explained by the measurement standard deviation [11)].

- Second case
  The repeatability standard deviation is of the same order of magnitude as or larger than the sampling standard deviation. In this case decisions on acceptability are to be based on calculations which take both sources of variation into consideration.

  An optimized control strategy can be developed using the following formula :

  $$\sigma_{\bar{x}} = \sqrt{\sigma_s^2 / n_1 + \sigma_r^2 /(n_1 n_2)}$$

  $\sigma_{\bar{x}}$: standard deviation of the arithmetic mean of test results
  σ_s : sampling standard deviation
  σ_r : repeatability standard deviation
  n_1 : sample size
  n_2 : number of measurements per sample unit.

This formula allows to determine the effect of sample size variation and variation of the number of replicate measurements on the standard deviation of the arithmetic mean of test results.
These Guidelines do not address how to take measurement uncertainty into consideration.

- General remark :
  Even in cases where the repeatability standard deviation is negligible compared to the sampling standard deviation (first case, see above), it should be kept in mind that between-laboratory measurement uncertainty (expressed as reproducibility standard deviation) may have to be taken into consideration, when evaluating results. This source of variation is not affected by the sample size and the number of replicate measurements per sample unit, while an increased sample size and an increased number of

replicate measurements per sample unit lead to a reduction of the standard deviation of the arithmetic mean of test results.

FINLAND

The **Draft General Guidelines on Sampling** are very welcome and are in accordance with the principles of the standard ISO/IEC 17025 "General requirements for the competence of testing and calibration laboratories". However, we note that the Guidelines *recommend* that the sampling is performed by persons trained in the techniques of sample collection (2.3.1). The ISO/IEC standard *requires* that personnel performing specific tasks shall be qualified on the basis of appropriate education, training, experience and/or demonstrated skills, as required (5.2.1).

HUNGARY

We have experienced that most of our earlier suggestions were accepted and the mistakes corrected. Unfortunately , some errors in the marking could be found on the tables and in the text, respectively. It is very important, that the marking should be consistent.

Page 57. Recommended sampling plans by variables: s method

In the text the acceptance constant is denoted with K. Page 59. In Table 14 and Page 68. In Table 17 the same acceptance constant is denoted with k. It will be better to use everywhere K since this could be found in all other tables.

The system of the headings in the tables should be always the same. (Eg Table 14 and 17.)

We hope these little corrections make the application of sampling plans for the user more understandable.

JAPAN

We acknowledge that great improvements in user-friendliness and usability were made at the last session. However, we believe it still not so easy for government offices to select an appropriate sampling plan if no officer knowledgeable of the ISO sampling standards is available. In order to further improve the user-friendliness and usability of the document, we wish to offer the following suggestions.

Specific comments

2.2.5 Total estimation error

It would be helpful to readers if an example(s) of "other errors" is(are) added. It will be especially helpful when these "other errors" are regarded as important as those errors included as clearly specified in the list of errors.

2.2.11 Defects (Nonconformities) and Critical Nonconformities

It would be helpful to readers if judgment criteria or practical examples, as shown in section 3.2.3, for classifying nonconformities into Class A and Class B as the term "seriousness", "highest concern" or "less important" does not provide sufficiently clear guidance for the classification.

2.2.13 Producers' risk and consumers' risk

The current definition of the term "discrimination distance" does not allow us to estimate discrimination distance. We believe it necessary to include a formula for estimating a discrimination distance.

2.2.18 Lot Size and Sample Size

We think it very helpful and useful if the section contains more examples for sample size and sample number.

2.4 ESTIMATION ERRORS

The last sentence in page 51 states that it is desirable that the sampling errors associated with any sampling plan, as well as the measurement errors associated with the analysis should be quantified and minimized. We believe it helpful to include the references or methods for quantifying sampling errors and measurement errors.

NEW ZEALAND

New Zealand welcomes the development of these guidelines and supports their finalisation.

Section 2.4, Estimation errors. The last paragraph of this section, referring to the case where measurement error is larger than sampling error, should be amended. Even when measurement error exceeds sampling error statistical principles must still be followed to ensure a fair and valid assessment is made, but it is true that sampling error does not need to be considered in these cases. It should be stated that in these instances the plans in the current guidelines do not apply.

UNITED STATES

In response to the CL 2003/29-MAS, the United States of America respectfully notes that the proposed draft document appears to have addressed most of the previous comments. However, the current text needs to be closely edited to clarify, facilitate translation, or avoid confusion in interpretation of the document. Following are some editorial/general comments on the document.

General Comments

1) Page 36, Flow-Chart for Chemical and Physical Characteristics,
    i) Qualitative and Quantitative characteristics, change "E.g.:" to "E.g.,"
    ii) Quantitative characteristics, isolated lots, bulk, change "Sampling by variables" to "To be sampled by variables sampling plans for isolated lots."
    iii) Quantitative characteristics, continuous series of lots, bulk, change "Sampling by variables" to "To be sampled by variables sampling plans for a continuous series of lots."
    iv) Quantitative characteristics, isolated lots, item, change "Sampling by attributes" to "To be sampled by attribute sampling plans for isolated lots."
    v) Quantitative characteristics, continuous series of lots, item, change "Sampling by attributes" to "To be sampled by attribute sampling plans for a continuous series of lots."
    vi) Quantitative characteristics, continuous series of lots, item, change "or by variables" to "or by variables sampling plans for a continuous series of lots."
2) Page 37, Flow-Chart for Microbiological Characteristics
    i) Qualitative and Quantitative characteristics, change "E.g.:" to "E.g.,"
3) Page 40, Table 1, first column, change "Example: check tank of milk **to** for added water" to "Example: check tank of milk for added water."
4) Page 43, 2.1.2, fourth black bullet, second line, delete period in sentence, i.e., change "… sample **.**may still …" to read as "… sample may still …"
5) Page 52, General case, statement in parentheses,"(e.g., analytical error is at most 1/3 of sampling error, then the standard deviation for the observed results will be less than 5% than the standard deviation without taking into account the analytical error)" should read as (e.g., if the analytical error is at most 1/3 of sampling error, then the standard deviation for the observed results will be **at most** 5 % **larger** than the **sampling** standard deviation taking into account the analytical error)."
6) Page 52, First specific case, change "In such case, the standard for the observed results will be less than 41 % than the standard deviation without taking into account the analytical error." To In such case, the standard for the observed results will be **at most** 41 % **larger** than the **sampling** standard deviation taking into account the analytical error."
7) Page 52, foot note 11, change "… or an increase of 5 %." to "… or an increase of 5 % over the sampling standard deviation."
8) Page 52, foot note 12, change "… or an increase of 41 %." to "… or an increase of 41 % over the sampling standard deviation."
9) Page 54, change "The inspection consists of measuring …, then in calculating the mean value x of these n items in the sample." to "The inspection consists of measuring …, then in calculating the mean value

$(\bar{x})$ of these n items in the sample." **Note:** This change is needed to support the results presented in Table 3.

10) Page 56, 2.5.1.2.4, change "Comparison of σ and s methods" to "Comparison of σ- and s-methods"

11) Page 56, footnote 13, change "σ method" to "σ-method" in both places mentioned.

12) Page 58, Figure 3, Title, change "Compared OC curves… "to "Comparison of OC curves**." Note: check to see if OC is previously defined.**

13) Page 58, Figure 3, Graph title, change "Compared OC curves of variable sampling plans: method s and method sigma…" to "Comparison of OC curves of variable sampling plans: s-method and σ-method…"

14) Page 58 Figure 3, Graph plot identifications, change "s method and sigma" to "s-method and σ-method.

15) Page 58, Table 5, delete space, i.e., change "σ -method" to"σ-method."

16) Page 59, Figure 4, Title, change "Compared OC curves… "to " Comparison of OC curves."

17) Page 58, Figure 4, Title, change "Compared operating characteristic curves… " to " Comparison of operating characteristic curves."

18) Page 60, 2.5.1.4, the decision tree carries over to page 61 without proper identification. Need to fit tree on one page if possible.

19) Page 62, Table 7, Title, should read as follows: "Table 7 Comparison of sample sizes for attribute and variable sampling plans (normal inspection level) by Sample Size and Code Letter"

20) Page 63, 2.6 Cost of Sampling, fourth line, delete period in sentence, i.e., change "…. financial losses .for the producer…" to "financial losses for the producer…"

21) Page 64, 3.1, Procedure A, second line, insert a "," after "i.e." to read "i.e.,"

22) Page 65, 3.2.1, Two-class Attribute Plans, define C_n^i to avoid any confusion with acceptance number definition.

23) Page 71, Table 9, third column, need carriage return between n=8, c=1 and P_{95} so that P_{95} appears on the second line as "P_{95} = 2,64%."

24) Page 76, Figure 6, bold horizontal line intended to indicate QL = 10% acceptance is too low.

25) Page 77, Figure 7, bold horizontal line intended to indicate QL = 10% acceptance is too low.

26) Page 79, Figure 8, bold horizontal line intended to indicate 50% acceptance or indifference quality needs to be defined as (IQ) or in a manner consistent with the way QL is defined.

27) Page 81, 4.3.1.1, change "'s' method" to "s-method."

28) Page 81, 4.3.1.2, change "'σ' method" to "σ-method."

29) Page 83, Table 15, columns 2 – 5, need carriage return to place AQL = 0,65% on second line under the appropriate code letter.

30) Page 85, Figure 10, title immediately above graphic figures, change "method s" to "s-method."

31) Page 86, Table 16, columns 2 – 5 need carriage return to place AQL = 2,5% on second line under the appropriate code letter.

32) Page 88, Figure 11, need to specify method, i.e., "s-method" or "σ-method" whichever is appropriate.

33) Page 88, Figure 12, title immediately above graphic figures, change "s method" to "s-method."

34) Page 89, 4.3.3.1, change "P_A is the probability to accept the lot having a defective rate p" to "P_A is the probability of accepting a lot having a defective rate of p."

35) Page 91, Table 18, columns 2 – 5, need carriage return to place AQL = 0,65% on second line under the appropriate code letter.

36) Page 93, Figure 13, title immediately above graphic figures, change “sigma method” to “σ-method.”

37) Page 93, Figure 13, change “Rate of non conforming items in lot” to “Rate of non-conforming items in the lot.”

38) Page 93, Figure 14, title immediately above graphic figures, change “sigma method” to “σ-method.”

39) Page 93, Figure 14, change “Rate of non conforming items in lot” to “Rate of non-conforming items in the lot.”

40) Page 96 Figure 15, title immediately above graphic figures, change “sigma method” to “σ-method.”

41) Page 96 Figure 16, title immediately above graphic figures, change “sigma method” to “σ-method.”